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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

7590 11/04/2004
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/627,531

Applicant(s)

BERRY ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27,29-31,33-41 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27,29-31,33-41 and 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/6/00 & 11/6/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 08/16/04. The communication filed 08/16/04 does not amend any of the pending claims. Claims 17-27, 29-31, 33-41 and 49-53 are pending.

Information Disclosure Statement

Applicants are inquiring about IDS filed July 28, 2000 and on or about November 1, 2000. Specifically IDS of 11/06/2000 and 11/06/2003 were considered and copies were mailed to applicants on 05/11/01 and 05/10/04. However, the copies will be re-forwarded to applicants with this action.

Claim Rejections - 35 USC § 112

1. The rejection of claims 33-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicants argue that the vehicle is single phase and a beneficial agent is suspended in the single phase vehicle. These claims will be included in the rejection in light of the explanation.

Claim Rejections - 35 USC § 102

2. Claims 17-19, 24-27, 29-31, 33, 36, 52 and 53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Daher et al. (US 4,376,118).

Applicants argue that Daher cannot anticipate the claims because Daher fails to disclose beneficial agent "as recited in claim 17" and as filed in the specification on page 11, line 21" ..., and further that Daher does not disclose the solvent as "lauryl lactate."

Applicants conclude that Daher does not expressly or inherently disclose each and every element of any of claims 17, 18 and 36 because Daher does not disclose beneficial agent as filed in the specification and does not disclose the solvent to be lauryl lactate.

3. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Regarding the description/definition of beneficial agent by the instant disclosure, it is noted that the generic claims do not recite those specific agents that applicants say is their invention. The generic claims claim broad beneficial agent and any beneficial agent would meet that limitation. Furthermore, it is noted that the features upon which applicants rely (i.e., beneficial agents disclosed in the instant disclosure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding lauryl lactate, it is respectfully noted that Daher discloses lauryl lactate as one of the components of the composition. Examiner agrees with applicants that Daher does not name lauryl lactate a solvent and although Daher fails to specifically name lauryl lactate a solvent, lauryl lactate is disclosed as a component of the composition. It appears that applicants suggest other functions/uses for the lauryl lactate. In the context of the composition, Daher meets the limitation of lauryl lactate as a solvent by a disclosure of the lauryl lactate even though Daher does not specifically say that lauryl lactate functions as a solvent. Secondly, in the absence of any showing disqualifying the lauryl lactate of Daher a solvent capable of functioning as a solvent, the future intended use/function of the lauryl lactate is not critical to the composition of Daher or the instant composition. How would lauryl lactate present in the prior

Art Unit: 1615

art not meet the limitations of lauryl lactate because the prior art does not describe it as such and applicants describe it a solvent?

However, in light of Daher's disclosure of a composition that contains a beneficial agent and lauryl lactate, Daher anticipates an instant composition that contains lauryl lactate and beneficial agent. Daher anticipates the designated claims.

Claim Rejections - 35 USC § 103

4. Claims 20 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118).

Applicants argue that Daher does not render obvious claims 20 and 21 because the independent claims are not obvious over Daher since Daher does not disclose the beneficial agents disclosed in the instant disclosure and does not also disclose lauryl lactate as solvent.

5. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Daher discloses beneficial agents and applicants rely on limitations (i.e., beneficial agents specifically disclosed in the instant disclosure) that are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding lauryl lactate, it is respectfully noted that Daher discloses lauryl lactate as one of the components of the composition.

6. Claims 34, 35, 40, 41 and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118).

Applicants argue that claims 40, 41 and 49 are non-obvious because these claims depend from non-obvious claim 17 and because claim 17 is non-obvious since Daher does not disclose or suggest beneficial agent according to the instant specification and Daher does not disclose lauryl lactate as a solvent.

7. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Daher discloses beneficial agents and applicants rely on limitations (i.e., beneficial agents specifically disclosed in the instant disclosure) that are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding lauryl lactate, it is respectfully noted that Daher discloses lauryl lactate as one of the components of the composition.

8. Claim 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of Jernberg (US 5,290,271).

Applicants argue that Daher does not disclose beneficial agent as described in the instant disclosure and does not disclose the use of lauryl lactate as a solvent.

9. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Daher discloses beneficial agents and applicants rely on limitations (i.e., beneficial agents specifically disclosed in the instant disclosure) that are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.

Art Unit: 1615

1993). Regarding lauryl lactate, it is respectfully noted that Daher discloses lauryl lactate as one of the components of the composition.

10. Claims 37 and 38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of GB 1,049,104.

Applicants argue that Daher does not disclose beneficial agent as described in the instant disclosure and does not disclose the use of lauryl lactate as a solvent.

11. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Daher discloses beneficial agents and applicants rely on limitations (i.e., beneficial agents specifically disclosed in the instant disclosure) that are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir.

1993). Regarding lauryl lactate, it is respectfully noted that Daher discloses lauryl lactate as one of the components of the composition.

12. Claims 50 and 51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of Bergy et al. (US 3,632,768).

Applicants argue that Daher does not disclose beneficial agent as described in the instant disclosure and does not disclose the use of lauryl lactate as a solvent.

13. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Daher discloses beneficial agents and applicants rely on limitations (i.e., beneficial agents specifically disclosed in the instant disclosure) that are not recited in the rejected claim(s).

Art Unit: 1615

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding lauryl lactate, it is respectfully noted that Daher discloses lauryl lactate as one of the components of the composition.

14. Claims 22 and 23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Daher et al. (US 4,376,118) in view of Bogdanský et al. (US 5,284,655).

Applicants argue that Bogdanský lists a laundry list of compounds for incorporation in osteogenic composition and in light of the laundry list, tetracycline and protein cannot be equivalent and as such tetracycline cannot be substituted for protein.

15. Applicants' arguments filed 08/16/04 have been fully considered but they are not persuasive.

Bogdanský is relied upon for a teaching of a composition that comprises glycerol monolaurate and tetracycline. Since there is another composition that contains glycerol monolaurate and protein and lauryl lactate, it would be obvious to make one that comprises glycerol monolaurate, lauryl lactate and tetracycline.

No claim is allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period


Art Unit: 1615

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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